Performing General Laboratory Instrument and Method Correlation Studies

Background

This document describes how to perform instrument and method correlations studies in the General Laboratory

Policy

- Correlation studies are performed at least twice a year for all non-waived analytes that are tested on more than one instrument and/or method
- Acceptance criteria are defined in Appendix A, except where noted otherwise. CAP acceptable limits are used when defined and appropriate for an analyte

Supplies and Equipment

Analyzers, equipment, their associated reagents, and supplies listed below will be used in correlation studies

- Abbott i-Stat analyzer
- Hematek 2000 Auto stainer
- InCyto manual counting chamber
- Microscope
- Quidel Sofia analyzers
- Refractometer
- Roller 20 Auto ESR
- Siemens Dimension Vista 1500 analyzers
- Stago STA Compact analyzers
- Sysmex XE-2100 and XE-5000 analyzers
- iChem 100 UA analyzer
- iRICELL 3000 UA analyzer
- Streck ESR Auto Plus analyzer

Specimen

Specimen types listed below may be used as applicable to each method.

- Whole blood (Li heparin, Na heparin and/or EDTA.)
- Plasma (Li heparin, Na heparin, Na Fluoride/potassium oxalate.)
- Random patient urine containing appropriate analytes
- Body fluids (CSF, synovial, pleural, ascites)

NOTE: Use of human specimens is preferred. If stability of patient samples is a limiting factor, use of Quality control data may be used for comparison of tests performed on same instrument platform, with both control materials and reagents of same manufacturer and lot number. Refer to QMP document *Proficiency Testing Program* for restrictions on use of PT material. Quality control data may not be used for method comparison performed on different instrument platforms.

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Procedure A Manual body fluid Count to Sysmex 5000 Auto body fluid count correlation

Step	Action
1	Obtain body fluid specimen suitable for analysis on Sysmex XE-5000 analyzer.
2	• Run sample on Sysmex XE-5000 analyzer • Verify counts and differential are valid and not flagged.
3	Perform manual cell count specimen using validated counting chamber
4	Prepare and stain slide for manual differential on same specimen
5	• Perform manual differential on slide • Combine lymphocyte and monocytes results to produce % mononuclear cell result • Combine neutrophil and other granulocytic cell results (i.e. eosinophils) to produce % PMN result
6	• Compare fluid RBC count, fluid WBC count, % PMN and % MONO between analyzer and manual results • Refer to Appendix A to determine acceptability
7	Section Supervisor/Lab Manager to review results for acceptability

Procedure B Manual WBC differential to Sysmex 5000/2100 Auto WBC differential correlation

Step	Action
1	Select one previously resulted patient EDTA whole blood sample with values within ranges listed below: • WBC=5.0-20.0 RBC=3.50-5.50 • HGB=7.0-15.0 HCT=21.0-45.0 • MCV=70-110 RDW= <16.4 • PLT=100-500 NEUT=40-75% • LYMP=20-50% MONO=5-15% • EOS=1-5% BASO=0-2%

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Procedure B, cont

Step	Action
2	• Run sample on Sysmex XE-5000 or XE 2100 analyzer • Verify counts and WBC differential are valid and not flagged
3	Prepare and stain slide for manual WBC differential on same specimen
4	Perform manual WBC differential on slide
5	• Compare 5 part differential between analyzer and manual results • Refer to Appendix A to determine acceptability
6	Section Supervisor/Lab Manager to review results for acceptability

Procedure C Roller 20 Auto ESR analyzer to Streck Auto Plus ESR analyzer correlation

Step	Action
1	Select 20 EDTA whole blood specimens with sufficient volume for testing on both systems
2	Run specimens on Roller 20 ESR analyzer
3	Run same specimens on Streck Auto Plus ESR analyzer
4	• Compare applicable results between methods • Refer to Appendix A to determine acceptability
5	Section Supervisor/Lab Manager to review results for acceptability

Procedure D Quidel Sofia analyzer (1) to Quidel Sofia analyzer (2) correlation

Step	Action
1	Select one positive patient specimen and one negative patient specimen for Sofia Influenza A+B FIA Note: Due to seasonal fluctuations in prevalence, positive specimens may not be available. Select CAP specimens if necessary

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Procedure D, cont

Step	Action
2	Run specimens on both Quidel Sofia analyzers
3	• Compare results between analyzers • Refer to Appendix A to determine acceptability
4	Section Supervisor/Lab Manager to review results for acceptability

Procedure E Stago STA Compact (A) to Stago STA Compact (B) correlation

Step	Action
1	Refer to QMP document *Performing Correlation Studies, Coagulation*
2	Section Supervisor/Lab Manager to review results for acceptability

Procedure F Sysmex XE 5000 Hematology analyzer to Sysmex XE 2100 Hematology analyzer correlation study

Step	Action
1	Refer to SRMC document *Performing Instrument to Instrument Correlation on the Sysmex Hematology analyzer*
2	Section Supervisor/Lab Manager to review results for acceptability

Procedure G Siemens Vista (A) to Siemens Vista (B) correlation

Step	Action
1	Refer to SRMC document *Performing Instrument & Method Correlation Studies in Chemistry/Urinalysis*
2	Section Supervisor/Lab Manager to review results for acceptability.

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Procedure H iRICELL 3000 to iChem 100 correlation

Step	Action
1	Refer to SRMC document *Performing Instrument & Method Correlation Studies in Chemistry/Urinalysis*
2	Section Supervisor/Lab Manager to review results for acceptability.

Procedure I iRICELL 3000 to Refractometer correlation

Step	Action
1	Refer to SRMC document *Performing Instrument & Method Correlation Studies in Chemistry/Urinalysis*
2	Section Supervisor/Lab Manager to review results for acceptability.

Procedure J Abbott i-Stat to Siemens Vista Correlation

Step	Action
1	Refer to SRMC document *ISTAT Comparison with Siemens Analyzer*
2	Section Supervisor/Lab Manager to review results for acceptability.

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Results Review

- If initial results exceed acceptable correlation criteria for an analyte are not acceptable, testing may be repeated on additional samples. If repeat correlation is still unacceptable, corrective action may be needed after investigation.
- QC results, calibration history, maintenance records, service reports, and error logs may be examined as part of the investigation. Original method verification studies may also be referenced. Corrective action may include (but is not limited to) maintenance, reagent replacement, calibration, consultation with vendor technical and service specialists, and vendor instrument service.
- Additional worksheets with post corrective action acceptable results and corrective actions will be submitted along with the initial results. Corrective actions will be documented
- Section Supervisor or Lab Manager will review/approve correlation study results and will be filed in the appropriate binder

Related Documents

- Appendix A: Acceptance Criteria for Performing General Laboratory Instrument and Method Correlations

References

- Manufacturer's operator's manual
- Manufacturer's product notification documents

End